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Gene Editing Panel Discussion– U.S. Environmental Protection Agency

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In September 2016, EPA indicated in the National Strategy for Modernizing the Regulatory System for Biotechnology Products (put forward by the United States EPA, USDA, and FDA) that it intends to clarify its approach to pesticidal products derived from genome editing.

EPA has exempted plant-incorporated protectants (PIPs) from sexually compatible plants that occur naturally in the plant or are moved through conventional plant breeding (40 CFR 174.25) from the United States Federal Insecticide, Fungicide, and Rodenticide (FIFRA) requirements, e.g. for product registration/licensing and field testing.

EPA has also exempted residues of plant-incorporated protectants (PIPs) from sexually compatible plants that occur naturally in the plant or are moved through conventional plant breeding (40 CFR 174.508) from the United States Federal Food, Drug and Cosmetic Act (FFDCA) tolerance requirements, e.g. for pesticide residues in food or feed, provided the residues are not present in food at levels that are injurious or deleterious to human health.

It has been argued that PIPs identical to these exempted PIPs created using CRISPR / Cas9 and similar techniques also fall within the 40 CFR 174.25 exemption. However, when this exemption was written in 2001, CRISPR / Cas9 (SDNs) did not exist as a gene editing technique.

EPA is now working towards removing PIPs that are equivalent to PIPs that occur naturally in plants and can be moved through conventional plant breeding from EPA oversight through rulemaking, which will be initiated this fall and moved expeditiously through the process.

In the interim, EPA will soon be launching a pilot program this fall to provide expedited review of PIPs that are equivalent to those that occur naturally in plants and can be moved through conventional plant breeding.

Expedited Review

EPA will quickly review PIP registration applications for genome edited PIPs that are equivalent to those that occur naturally in plants and can be moved through conventional plant breeding. Less data will also be required. Although EPA's review timeframe under PRIA continues to be 13 months for these actions, we will generally do our best to make a registration decision for these PIPs in as little as 4 months. We will primarily only need product characterization and use history and not the other data typically required for PIPs, e.g. acute toxicity, in vitro digestibility, non-target organism toxicity, and environmental fate.